

REMARKS

I. Claims

Claims 1 and 4-47 are currently pending. Claims 1 and 4-44 stand rejected. Claims 45-47 are newly added. Claims 1, 4-8, and 20-26 are now amended. Reconsideration of the above-identified application in view of the amendments to claims 1, 4-8, and 20-26 and the following remarks is respectfully requested.

1. Rejection of Claims 7 and 25 Under 35 U.S.C. §112

Claims 7 and 25 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states that claims 7 and 25 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 7 recited that "one of said first retaining member and said first mounting member includes a stop", and claim 25 included a similar recitation. According to the Office Action, the only mention of a "stop" in the specification relates to stops on the retaining members, and there is no mention of either of the mounting members containing a stop. Claims 7 and 25 are now amended in a manner believed to overcome this rejection. Claims 8 and 26 are also now amended in a manner to reflect the amendments to claims 7 and 25. Reconsideration of this rejection of claims 7 and 25 is respectfully requested.

2. Rejection of Claims 1-3, 5-13, 16-21, 23-29 and 32-34 Under 35

U.S.C. §102(b)

Claims 1-3, 5-13, 16-21, 23-29 and 32-34 have been rejected as anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,893,889 to Harrington (hereinafter, "Harrington"). Claim 1 has been amended to include the subject matter of claims 2 and 3 and a portion of the subject matter of claim 4. Claims 2 and 3 have been cancelled, and claim 4 has been amended. It is respectfully submitted that amended claim 1 and claims 5-13, 16-21, 23-29 and 32-34 are novel over Harrington.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

Claim 1, as amended, recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises an artificial disc that includes a resilient core having a first surface and a second surface. A first retaining member is connected to the first surface of the resilient core. A second retaining member is connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with a second vertebra of the spinal column and an

inner surface facing the second surface of the resilient core. The outer surfaces of the first and second retaining members face away from each other. A first mounting member is connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member is engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. The first retaining member includes a guide with an outer surface that extends outwardly from the outer surface of the first retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

The Office Action states that Harrington discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Harrington comprises an artificial disc (disc 18 of Harrington) that includes (a) a resilient core (member 68 of Harrington) having a first surface and a second surface, (b) a first retaining member (member 32 of Harrington), and (c) a second retaining member (member 34 of Harrington). The Office Action also states that the first retaining member of Harrington has an outer surface (surface 36 of Harrington) and an inner surface (surface 58 of Harrington) and that the second retaining member of Harrington has an outer surface (surface 40 of Harrington) and an inner surface (surface 44 of Harrington). Further, according to the Office Action, the apparatus of Harrington comprises a first mounting member (screws 64 and 66 of Harrington) connectable with the first vertebra to position the artificial disc between the first and second vertebrae and engageable with the artificial disc after

being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. Lastly, with respect to claims 2 and 3, the Office Action asserts that the first retainer member of Harrington (member 32 of Harrington) includes a guide (see angled openings of holes 60 of Harrington) engageable with the first mounting member of Harrington (screws 64 and 66 of Harrington).

It is respectfully submitted that Harrington does not anticipate the apparatus of claim 1, as amended, in that each and every element recited in claim 1 is not disclosed by Harrington as required by 35 U.S.C. §102(b). Specifically, amended claim 1 recites a guide with an outer surface that extends outward from the outer surface of the first retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae. The recessed, angled openings of holes 60 of Harrington, which the Office Action asserts are the guide of claim 1, do not have an outer surface that extends outward from the outer surface of the member 32 of Harrington, which the Office Action asserts is the first retainer member of claim 1. Since Harrington does not disclose this element of amended claim 1, Harrington cannot anticipate claim 1 under 35 U.S.C. §102(b). Amended claim 1 is therefore novel and allowable over Harrington.

Claims 5-13, 16-21, 23-29 and 32-34 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of amended claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 5-13, 16-21, 23-29 and 32-34 define over

Harrington, and withdrawal of this rejection of claims 5-13, 16-21, 23-29 and 32-34 is respectfully requested.

3. Rejection of Claims 1-4, 19-22, 35-36 and 39-40 Under
35 U.S.C. §102(b)

Claims 1-4, 19-22, 35-36 and 39-40 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,156,067 to Bryan et al. (hereinafter, "Bryan"). Claim 1 has been amended to include the subject matter of claims 2 and 3 and a portion of the subject matter of claim 4. Claims 2 and 3 have been cancelled, and claim 4 has been amended. It is respectfully submitted that amended claims 1 and 4 and claims 19-22, 35-36 and 39-40 are novel over Bryan.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 927 F.2d 1565 18, USPQ2d 1001 (Fed. Cir. 1991).

Claim 1, as amended, recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises an artificial disc that includes a resilient core having a first surface and a second surface. A first retaining member is connected to the first surface of the resilient core. A second retaining member is connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with a first vertebra of the spinal column and an inner

surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface facing the second surface of the resilient core. The outer surfaces of the first and second retaining members face away from each other. A first mounting member is connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member is engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. The first retaining member includes a guide with an outer surface that extends outwardly from the outer surface of the first retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

The Office Action states that Bryan discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Bryan comprises an artificial disc that includes (a) a resilient core (central portion 24 of body 20 of Bryan) having a first surface and a second surface, (b) a first retaining member (support 32 of Bryan), and (c) a second retaining member (support 34 of Bryan). The Office Action also states that the first retaining member of Bryan has an outer surface (surface 52 of Bryan) and an inner surface (surface 62 of Bryan) and that the second retaining member of Bryan has an outer surface (surface 54 of Bryan) and an inner surface (surface 64 of Bryan). Further, according to the Office Action, the apparatus of Bryan comprises a first mounting member (screw 92 of Bryan) connectable with the first vertebra to position the

artificial disc between the first and second vertebrae and engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. Lastly, with respect to claims 2, 3 and 4, the Office Action asserts that the first retainer member of Bryan (support 32 of Bryan) includes a guide (see screw anchor 102 of Bryan) that is engageable with the first mounting member of Bryan (screw 92 of Bryan) and that extends from the outer surface (see surface 52 of Bryan) of the first mounting member of Bryan.

It is respectfully submitted that Bryan does not anticipate the apparatus of amended claim 1 in that each and every element recited in claim 1, as amended, is not disclosed by Bryan as required by 35 U.S.C. §102(b). Specifically, as shown in Fig. 3 of Bryan, the screw 92 of Bryan, which the Office Action asserts is the "mounting member" of Bryan, engages a threaded inner surface of the anchor 102, which the Office Action asserts is the "guide" of Bryan. The anchor 102 of Bryan is also disposed adjacent to a surface of a leg 72 of the support 32, which the Office Action asserts is the first retaining member of Bryan. The surface of the leg 72 of the support 32 of Bryan extends generally perpendicularly to surfaces 52 and 62 of another leg 42 of the support 32 and to surfaces 54 and 64 of one leg 44 of the support 44 of Bryan. The surfaces 52 and 62, according to the Office Action, are the outer and inner surfaces of the first retaining member of Bryan and the surfaces 54 and 64 are the outer and inner surfaces of the second retaining member of Bryan.

In contrast to Bryan, the first retaining member of amended claim 1 includes a guide with an outer surface that extends outwardly from the outer surface of the first

retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae. Claim 1, as amended, also recites that the outer surface of the first retaining member, from which the outer surface of the guide extends, faces away from the outer surface of the second retaining member. This contrasts with the orientation of the surfaces of Bryan in which the anchor 102, which the Office Action asserts is the guide of Bryan, is disposed adjacent to and extends away from a surface of a leg 72 that is oriented generally perpendicular to both the asserted outer surface 52 of the first retaining member 42 of Bryan and the asserted outer surface 54 of the second retaining member 44 of Bryan. Since Bryan thus does not disclose these elements of amended claim 1, Bryan cannot anticipate claim 1 under 35 U.S.C. §102(b). Amended claim 1 is therefore novel and allowable over Bryan.

Claims 4, 19-22, 35-36 and 39-40 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the immediately preceding discussion of amended claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 4, 19-22, 35-36 and 39-40 define over Bryan, and withdrawal of this rejection of claims 4, 19-22, 35-36 and 39-40 is respectfully requested.

4. Rejection of Claims 37 and 38 Under 35 U.S.C. §103(a)

Claims 37 and 38 have been rejected as unpatentable under 35 U.S.C. §103(a) over Bryan in view of U.S. Patent No. 4,309,777 to Patil (hereinafter, "Patil"). It is respectfully submitted that claims 37 and 38 define over the cited art.

The Office Action states that Bryan discloses an apparatus as defined in claim 1 but does not teach a flange located on the retaining members. According to the Office Action, Patil teaches an intervertebral disc wherein a first retaining member (disc portion 12 of Patil) includes a flange extending toward a second retaining member (disc portion 14 of Patil) and having a radially inner surface facing a core (compression springs 16 of Patil) and spaced from the core. The Office Action also states that Patil's second retaining member (disc portion 14 of Patil) includes a flange extending toward the first retaining member (disc portion 12 of Patil) and having a radially inner surface facing the core and spaced from the core. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the retaining members 42 and 44 of Bryan to include a flange extending toward the other retaining member, as suggested by Patil, as doing so would restrict the amount of compression of which the core is capable and allow the resulting apparatus to more closely imitate the natural motion of the vertebrae.

As previously explained with respect to the rejection of amended claim 1 as being anticipated under 35 U.S.C. §102(b) by Bryan, Bryan does not disclose the apparatus of amended claim 1, and claim 1 is novel over Bryan. Claims 37 and 38 depend, directly or indirectly, from amended claim 1, and are allowable for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(b) by Bryan and further for the recitations contained in those claims. It is thus respectfully submitted that claims 37 and 38 define over the cited art, and withdrawal of the rejection of claims 37 and 38 is respectfully requested.

5. Rejection of Claims 41-44 Under 35 U.S.C. §103(a)

Claims 41-44 have been rejected as unpatentable under 35 U.S.C. §103(a) over Harrington in view of U.S. Patent No. 5,314,477 to Marnay (hereinafter, "Marnay"). It is respectfully submitted that claims 41-44 define over the cited art.

The Office Action states that Harrington discloses an apparatus as defined in claim 1 but does not teach retaining members engageable with a surgical tool. According to the Office Action, with respect to claims 41 and 43, Marnay teaches an intervertebral disc prosthesis wherein a first retaining member (plate 110 of Marnay) includes a portion (holes 115 and 116 of Marnay) engageable with a surgical tool and having an opening into which a portion (rods 812 and 813 of Marnay) of a surgical tool extends. Also, according to the Office Action, with respect to claims 42 and 44, Marnay teaches an intervertebral disc prosthesis wherein a second retaining member (plate 120 of Marnay) includes a portion (holes 125 and 126 of Marnay) engageable with a surgical tool and having an opening into which a portion (rods 822 and 823 of Marnay) of a surgical tool extends. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the retaining members 32 and 34 of Harrington to include openings for a surgical tool, as suggested by Marnay, to facilitate insertion of the artificial disc into the intervertebral space.

As previously explained with respect to the rejection of amended claim 1 as being anticipated under 35 U.S.C. §102(b) by Harrington, Harrington does not disclose the apparatus of amended claim 1, and claim 1 is novel over Harrington. Claims 41-44 depend, directly or indirectly, from amended claim 1, and are allowable

for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(b) by Harrington and further for the recitations contained in those claims. It is thus respectfully submitted that claims 41-44 define over the cited art, and withdrawal of the rejection of claims 41-44 is respectfully requested.

6. Rejection of Claims 1, 14-15, 19 and 30-31 Under 35 U.S.C. §103(a)

Claims 1, 14-15, 19 and 30-31 have been rejected as unpatentable under 35 U.S.C. §103(a) over U.S. Patent Application Publication 2004/0122517 to Kuras (hereinafter, "Kuras") in view of U.S. Patent No. 6,086,613 to Camino et al (hereinafter, "Camino") and European Patent Application EP 1 285 632 to Forriol Pico (hereinafter, "Forriol Pico"). It is respectfully submitted that amended claim 1 and claims 14-15, 19 and 30-31 define over the cited art.

Pursuant to 35 U.S.C. §103, even though the invention is not identically disclosed or described as set forth in 35 U.S.C. §102, a patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. When considering nonobviousness under 35 U.S.C. §103, the U.S. Supreme Court held in Graham v. John Deere Co., 383 U.S. 1 (1966) that:

- a) that the scope and content of the prior art are to be determined;
- b) the differences between the claims at issue and the prior art are to be ascertained; and
- c) the level of ordinary skill in the pertinent art is to be resolved.

The Office Action states that Kuras discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Kuras comprises an artificial disc that includes (a) a resilient core (core 60 of Kuras) having a first surface and a second surface, (b) a first retaining member (retaining member 20 of Kuras), and (c) a second retaining member (retaining member 40 of Kuras). The Office Action also states that the first retaining member of Kuras has an outer surface and an inner surface and that the second retaining member of Kuras has an outer surface and an inner surface. Further, according to the Office Action, the first and second retaining members of Kuras have axially extending openings (openings 30 and 50 of Kuras). The Office Action notes that Kuras fails to teach the use of first and second mounting members. The Office Action then states that Camino teaches an apparatus wherein a central portion (spacer 12 of Camino) is attached to vertebrae through the use of upper and lower mounting members (end caps 10 of Camino) and that Forriol Pico teaches a bone plate wherein the mounting members (screws of Forriol Pico) are inserted prior to insertion of the plate. Therefore, the Office Action asserts, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Kuras with first and second mounting members, as suggested by Camino, in the axially extending openings of Kuras, as doing so would allow the surgeon to visualize the site where he would be placing the mounting members and then use the mounting members as indicators of where the disc would be positioned.

As set out previously with respect to the rejections of claim 1 as being anticipated under 35 U.S.C. §102(b) by Harrington and by Bryan, amended claim 1

recites a guide with an outer surface that extends outwardly from the outer surface of the first retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae. The hypothetical modification of the apparatus of Kuras in view of Camino and Forriol Pico set out the Office Action would not result in such a guide nor is there any teaching or suggestion in Kuras, Camino or Forriol Pico to modify the apparatus of Kuras to provide such a guide. Claim 1, as amended, is therefore neither suggested nor taught by the proposed combination of references and is allowable over the cited art.

Claims 14-15, 19 and 30-31 depend, directly or indirectly, from amended claim 1, and are allowable for at least the reasons given in the preceding discussion of claim 1 and further for the recitations contained in those claims. It is therefore respectfully submitted that claims 14-15, 19 and 30-31 define over the cited art, and withdrawal of this rejection of claims 14-15, 19 and 30-31 is respectfully requested.

7. Newly Presented Claims 45-47

Claims 45-47 depend from amended claim 1, and are allowable for at least the reasons given in the preceding discussions of claim 1 and further for the recitations contained in claims 45-47. It is therefore respectfully submitted that claims 45-47 define over the cited art, and allowance of claims 45-47 is respectfully requested.

II. Conclusion

In view of the foregoing amendment and remarks, it is respectfully submitted that claims 1 and 4-47 define over the cited art. Withdrawal of the rejections of the claims and the passage of the application to issue is therefore requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,


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